EPO
Epidemiology Program Office
Issue 6

ADS Newsletter
Office of the Associate Director for Science
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CDC/ATSDR Policy on Releasing and Sharing Data

CDC believes that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. The new policy was issued on April 16, 2003.

The purpose of CDC's data release/sharing policy is to ensure that (1) CDC routinely provides data to its partners for appropriate public health purposes and (2) all data are released and/or shared as soon as feasible without compromising privacy concerns, federal and state confidentiality concerns, proprietary interests, national security interests, or law enforcement activities.

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Update: *The Health Insurance Portability and Accountability Act of 1996 Privacy Rule* (HIPAA Privacy Rule)

As the April 14 compliance deadline approached, the EPO-based CDC Privacy Rule Team was involved in a number of training and outreach activities to assist CDC employees and other public health providers with HIPAA preparation.

The most significant effort was the development of an MMWR R&R titled *HIPAA Privacy Rule: A Guidance for Public Health*. The guidance document was released online on April 11, 2003 immediately before the April 14 compliance date. The guidance document is intended to help public health agencies and others understand and interpret their responsibilities under the Rule. EPO staff anticipates that the document will serve as a timely and valuable resource for public health officials as well as covered entities.

The Privacy Rule Team has also been actively engaged in educational activities for CDC employees and CDC partners. In an effort to educate CDC employees, the Privacy Rule Team has sponsored four Privacy Rule forums since January. Each forum focused on a specific issue associated with the new regulations:

- The Impact of the Rule on Public Health Practice;
- The Impact of the Rule on Research;
- State Health Departments and the Privacy Rule; and
- The Range of Permissible Disclosures and the Impact of the HIPAA Privacy Rule on Health Care Providers.

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Ethical Dilemmas in Public Health

Clarification – In Issue 3, one of the ethical dilemmas described the following situation: a non-CDC co-author submitted an abstract to a conference without informing the CDC co-author. How should CDC respond? The previous response stated that the abstract must still be reviewed at CDC, and if not approved, must be withdrawn.

However, a more accurate response is:

"The abstract still must be reviewed and approved at CDC. If it is not subsequently cleared,(i.e. after the fact at CDC), then the CDC author must remove his/her name. CDC may only withdraw the CDC author's name, not the abstract."

Scenario 1 – In a rush to meet a deadline, an author decided to sign off for a co-author, and submitted the manuscript for clearance.

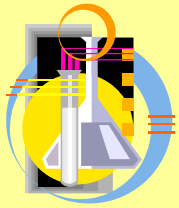
Can one author sign on behalf of another co-author?

NO. It is never acceptable for one author to sign on behalf of another.

What if the co-author gave their permission?

An author cannot sign for another author even with the coauthor's permission. All signatures must be genuine.

If you have ethical scenarios you would like to share, please submit them to Aun Lor (alor@cdc.gov).



Revised CDC/ATSDR Policy on Investigating Scientific Misconduct

CDC/ATSDR has revised the policy on Investigating Scientific Misconduct as requested by the Office of Research Integrity.

This policy provides guidance that enables allegations of scientific misconduct to be processed promptly and fairly. Additional information has been added to several existing sections of the policy and new subsections have been included as appropriate.

The CDC/ATSDR scientific misconduct policy and procedures apply to all scientific activities (e.g., human subjects research, non-human subjects research, technical assistance, emergency response, surveillance, screening, etc.,) conducted or proposed to be conducted by any CDC/ATSDR employee or trainee as part of his or her official duties or training. This policy and related policies of other agencies apply to CDC employees and trainees assigned outside of CDC by detail, inter-personnel agreement (IPA), or long-term training.

This policy can be accessed through the CDC Intranet at (http://basis1.cdc.gov/BASIS/masompb/POLICIES/POLICIES/DDD/247.)

Update: Health and Human Rights Workgroup (HHRW)

The Health and Human Rights Workgroup (HHRW) was initiated in July of 2001 in EPO, but has since broadened its activities to other parts of CDC. HHRW hopes to improve health and public health practice by working to incorporate fundamental human rights principles into public health activities and by educating public health workers about intrinsic linkages linkage between health and human rights. Currently the HHRW is working on several initiatives:

- **Health and Human Rights Lecture series** – HHRW is working on developing a lecture series focusing on health and human rights related topics. Some of the topics to be included in the lecture series include HIV/AIDS and Human Rights; War, Public Health and Human Rights; Refugee Health and Human Rights.
- **Guide to Developing a Public Health and Human Rights Impact Assessment** – HHRW recognizes that there is no formal guidance to protecting people in non-research activities. HHRW has developed a draft document, which includes an introduction on health and human rights principles, and sample tools that public health professionals may use or adapt to evaluate the potential impact public health program may have on health and individual and community rights.
- **Collaboration** – HHRW recognizes that there are many groups at CDC that are working on similar issues, e.g., Social Determinants of Health (SDOH), Behavioral and Social Science Workgroup (BSSWG), Measures of Racism Workgroup. HHRW hopes to work with these various groups at CDC to improve public health practice.

If you are interested in participating on the HHRW or just to get more information, please contact one of the HHRW co-chairs, Aun Lor (alor@cdc.gov or 404-639–1488) or Basia Tomcyzk (Btomczyk@cdc.gov or 770-488-3136).

Scientific Ethics Training

As a reminder, if you are planning to conduct research involving human subjects, you are required to take the CDC Scientific Ethics Training.

Each year, CDC and ATSDR scientists conduct several hundred studies throughout the world that involve people as research subjects. At the backbone of a strong public health science base is the practice of ethically responsible science. However, ethical issues encountered in public health research are different from those encountered in clinical medicine. To help ensure that our public health research is ethically grounded, a computer-based training program entitled *Scientific Ethics* has been developed. All scientific staff and managers will be required to complete the training before they conduct research at CDC or ATSDR. Upon completion of this training, CDC and ATSDR investigators will be better able to address ethical issues they encounter as they conduct research to improve the public's health.

If you have access to the CDC Intranet, the training can be taken online at http://intranet.cdc.gov/od/ads/ethicstrain.htm. A CD-ROM is also available from your EPO supervisor or the EPO ADS. After completing the training and taken the final exam, the investigator should submit their score along with the file "testres.txt" to their supervisor. This file will be automatically generated and store in the hard drive and can be found by searching through the c:drive. The supervisor will submit the ethics score to apply to obtain an ethics number.

Contact your EPO supervisor or Aun Lor (alor@cdc.gov) for more information.

Frequently Asked Questions

1. Does a bioterrorism-related presentation need clearance from the CDC Office of the Director?

All bioterrorism presentation slides must be sent for clearance to the CDC ADS office in the Office of the Director, CDC.

2. How do I contact the CDC Human Subjects Activity?

The CDC Human Subjects Activity (HSA) main line is (404) 498 – 3100. You may also contact HSA by email at huma@cdc.gov.

ADS Staff Update

The ADS Office would like to send their best wishes to **Denise Koo** in her new position as the Director of the Division of Applied Public Health Training (DAPHT). Denise has served as EPO ADS since August of 2001. We would also like to extend our best wishes to **Scott Kellerman**, who had served as the Deputy ADS. Scott will also be moving to DAPHT to continue his efforts in establishing the Office of Medical Education (OME).

We also wish to thank **Stephanie Zaza** for serving as the Interim ADS during March and April.

Announcements

Office of Human Research Protections (OHRP) Workshops

OHRP continues to sponsor a series of workshop on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies.

Date: June 4-6, 2003
Workshop Title: "PRIM&R & IRB101"; "Protecting Research Volunteers: Ethics & Practice"
Host: Tulane University
Place: New Orleans, LA

Date: July 22-24, 2003
Workshop Title: "Protecting Human Subjects in the 21st Century: Issues in Social & Behavioral Research"
Host: University of Georgia
Place: Athens, GA

Date: September 22-24, 2003
Workshop Title: "PRIM&R & IRB101" "Today's Research & Tomorrow's Issues"
Host: University of California, San Francisco
Place: San Francisco, CA

For further information regarding these workshops or future National Human Subject Protections Workshops, visit the OHRP website at http://ohrp.osophs.dhhs.gov/wrkshp.htm

Department of Health and Human Service Request for Public Comment

(April 2, 2003) HHS Secretary Tommy G. Thompson has proposed draft guidance for protecting research volunteers from possible harm caused by financial conflicts of interest in research. HHS is soliciting public comment on the draft guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" as announced in Federal Register, Vol.68, No. 61, Monday March 31, 2003, Page 15456. The notice can be accessed as a PDF document at: http://ohrp.osophs.dhhs.gov/references/fr03-7691.pdf.

Privacy Rule: Continued from page 1

These forums attracted large, audiences and were videotaped for future viewing. In the future, Privacy Rule Forums will be held on a monthly basis. Any suggestions for topics should be directed to Sal Lucido, CDC Privacy Rule Coordinator.

On March 28, the Privacy Rule Team held "Public Health Grand Rounds," in conjunction with the University of North Carolina (UNC) School of Public Health. Public health experts from the CDC, UNC, and Johns Hopkins gathered to share valuable insights about the HIPAA Privacy Rule. The event was broadcast via satellite to state and local public health partners throughout the world. As part of the broadcast, viewers had the unprecedented opportunity to interact with the presenters by participating in an interactive Q&A session by telephone or e-mail. UNC estimates that viewership for the session was approximately 4,000 people.

Finally, the CDC Privacy Rule website is up and running. Information on the impact of the HIPAA Privacy rule on covered entities, public health research, and a broad range of other issues related to the Privacy Rule can be found at www.cdc.gov/privacyrule.

For more information about any of these projects/programs, contact the CDC Privacy Rule Coordinator, Sal Lucido (Slucido@cdc.gov) or 404-639-3683.

Data Release: Continued from page 1

Data Covered by this Policy

This policy applies to any new data collection occurring 90 days or more following approval of this policy. Existing (previously established) data collections systems should be in compliance with this policy either within 3 years of policy approval (the cycle for surveillance and information system evaluation stipulated by the CDC Surveillance Coordination Group) or at the time of data system revisions, whichever occurs first.

The following data are covered by this policy:

- Data collected by CDC using federal resources.
- Data collected for CDC by other agencies or organizations (through procurement mechanisms such as grants, contracts, or cooperative agreements).
- Data reported to CDC (e.g., by a state health department).

Data Not Covered by this Policy

This policy does ***not*** cover data shared with CDC but owned by other organizations (e.g., data provided to CDC by a managed care organizations, preferred provider organizations, or technology firms for a specific research project). Such data may be covered by other policies or procedures that reflect pertinent laws, regulations, and agreements (such as the Freedom of Information Act.)

Guiding Principles

All CDC procedures on releasing or sharing data must be guided by the following principles.

- *Accountability* – As a public health agency of the U.S. government, CDC is acountable to the public and to the public health community for the data it produces through research.
- *Privacy and Confidentiality* – CDC recommends that, unless there is valid public health purpose (e.g., a longitudinal study that requires record linkage), programs should not collect nor maintain identifiable data.
- *Stewardship* – CDC holds data in public trust. Good stewardship of data requires that CDC release or share data in accordance with the objectives and conditions under which the data were collected or obtained and that appropriate policies and procedures for data release be set up.
- *Scientific Practice* - Before any data are released/shared, all phases of data collection, transmission, editing, processing, analysis, storage, and dissemination must be evaluated for quality.
- *Efficiency* - Releasing data to the public and sharing data with partners is an efficient way of ensuring that data are used to their full potential, that work is not duplicated, and that funds are not spent unnecessarily.
- *Equity* - CDC strives to have data release policies that are fair to all users, regardless of their organizational affiliation.

How to Release Data

All released data must be as complete and accurate as possible, and data must be released in accordance with the guiding principles set out in this document in one of two ways:

- Release for public use without restrictions.
- Release to particular parties with restrictions.

Restrictions can be imposed because of legal constraints or because releasing the data would risk (1) disclosing proprietary or confidential information, or (2) compromising national security or law enforcement interests.

CDC recommends that data be released in the form that is closest to microdata and that still preserves confidentiality.

Release of data for public use

Data that CDC collects or holds and that can be legally released to the public should be released through a public-use data set within a year after the data are evaluated for quality and shared with any partners in data collection.

CIOs may release data without restrictions for public use through the CDC Information Center. Data may also be shared through the CDC/ATSDR Scientific Data Repository, which is managed by CDC's Epidemiology Program Office. Finally, CIOs may respond to individual requests.

Data shared with restrictions

To the extent possible, CDC recommends sharing data that cannot be released for public use with public health partners. For such restricted data, special data sharing agreements must be developed. Below are two examples of how data can be shared with partners; these methods are not mutually exclusive:

- **Data release under controlled conditions*:*** Data that cannot be released through a public-use data set or a special-use agreement may be analyzed by appropriate non-CDC researchers at CDC-controlled data centers (e.g., the Data Center established at NCHS; see http://www.cdc.gov/nchs/r&d/rdc.htm for a description).
- **Data release through a special-use agreement*:*** Data that cannot be released publicly but that need not always be under CDC's control can be released to appropriate non-CDC researchers through a special-use agreement.

Appeals

Programs may petition not to have a particular data set released by appealing to the CDC's Deputy Director for Public Health Science.

For more information please refer to the *CDC/ATSDR Policy on Releasing and Sharing Data*: http://basis1.cdc.gov/BASIS/masompb/POLICIES/POLICIES/DDD/385.

EPO ADS Newsletter

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